K001734

MAR 2 6 2001

Edwards

510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person:	Diane Peterson, Senior Regulatory Affairs Specialist
Date Prepared:	December 21, 2000
Trade Name:	Fogarty® Valvulotome
Common Name:	Valvulotome
Classification Name:	External Vein Stripper/ Valvulotome (per 21 CFR 870.4885)
Predicate Devices:	Fogarty® Valvulotome (K965137)
Device Description:	The modified Fogarty® Valvulotome, like the predicate device, consists of a flexible shaft with a stainless steel cutting blade at the distal tip and a handle at the proximal end. The mode of operation for both devices is the same. The device is inserted into the vessel in an antegrade direction until the blade is located above the cusp of a venous valve. The location of the valve is visualized via an angioscope or is directly visualized through the vein wall in an open procedure. The blade is withdrawn retrograde through the cusp, thereby rendering it incompetent. After the blade disrupts one cusp, it is then rotated 180° to disrupt the adjoining cusp segment. The modified Fogarty® Valvulotome, like the predicate device, contains an irrigation lumen that provides irrigation/fluid flow during the valvulotomy procedure.
Indication for Use:	The modified Fogarty® Valvulotome, like the predicate device, is indicated for use in veins during in situ or autologous bypass graft procedures
Intended Use:	The modified Fogarty® Valvulotome, like the predicate device, is intended to be used in the disruption of venous valves.

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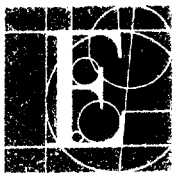

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Technological Comparison:	The modified Fogarty® Valvulotome, like the predicate device, consists of a flexible shaft with a stainless steel cutting blade at the distal tip and a handle at the proximal end. Both contain an irrigation lumen that provides irrigation/fluid flow during the valvulotomy procedure. The mode of operation for both devices is the same, as is the intended use. Therefore, the technological characteristics of the Fogarty® Valvulotome are equivalent to those of the predicate device.
Discussion of Non-Clinical Tests and Conclusions:	Biocompatibility and Functional/Bench testing was performed in the modified Fogarty® Valvulotome. Biocompatibility testing was performed in accordance with the requirements specified in International Standards Organization (ISO) 10993-1-1994 Biological Evaluation of Medical Devices – Part 1: Guidance on Selection of Tests and the FDA General Program Memorandum No: G95-1. The modified Fogarty® Valvulotome was found to be biocompatible and nontoxic and acceptable for its intended use. Functional testing was performed on the modified Fogarty® Valvulotome to evaluate the integrity and performance of the device. The testing demonstrated that the product meets its performance requirements for its intended use.
Conclusion:	The testing conducted on the modified Fogarty® Valvulotome demonstrates that it is safe and effective for its intended use and is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Edwards Lifesciences, LLC
c/o Ms. Diane Peterson
Senior Regulatory Affairs Specialist
One Edwards Way
Irvine, CA 92614

Re: K001734
Trade Name: Fogarty Valvulotome, Model 700091
Regulatory Class: II (two)
Product Code: MGZ
Dated: December 21, 2000
Received: December 26, 2000

Dear Ms. Peterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001734

Device Name: Fogarty® Valvulotome

Indications for Use:

The Fogarty® Valvulotome is indicated for use in veins during in situ or autologous bypass graft procedures.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001734

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)